Briefing for decision

Verification Pathway – finalising the rules and fees

Date due to MO:	7 May 2026	**Action required by:**	11 May 2026
Security level:	IN CONFIDENCE	**Reference:**	H2026082424
To:	Hon David Seymour, Associate Minister of Health		
Consulted:	Health New Zealand: ☐		
Proactive release:	This **title** is proposed by the Ministry of Health for proactive release: ☒		
Appendices:	Appendix 1 Draft Medicines (Fees) Amendment Regulations 2026 Appendix 2 LEG paper Appendix 3 Outcome of consultation – Verification Pathway Rules Appendix 4 Verification Pathway Rules		

Contact for telephone discussion

Name	Position	Telephone
Chris James	Group Manager, Medsafe	s9(2)(a)
Matthew Spencer	Manager, Product Regulation Branch, Medsafe	s9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Overtaken by events
☐ Needs change	☐ Seen	
☐ See Minister's Notes	☐ Withdrawn	

Comment:

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Purpose of report

1. This briefing attaches two papers required for completing the secondary legislation for the Verification Pathway.

Summary

2. Two pieces of secondary legislation are required to introduce the Verification Pathway:
   a. The Medicines Regulations must be amended to enable a fee to be charged for applications.
   b. You, as Associate Minister of Health, must agree to publish the rules.
3. Medsafe will be able to accept applications via the Verification Pathway as soon as the secondary legislation comes into effect. The indicative timeframe to enable regulations to come into effect on 4 July 2026 is detailed at the end of this document.

Recommendations

We recommend you:

a)	**Agree** to consult Ministers on the attached draft LEG paper and Medicines (Fees) Amendment Regulations 2026.	**Yes/No**
b)	**Agree** to lodge the LEG paper by 21 May for consideration by the Cabinet Legislation Committee on 28 May subject to any changes following consultation.	**Yes/No**
c)	**Note** the attached report on the results of consultation on the pathway rules	**Noted**
d)	**Agree** to the attached Medicines (Consent by Verification) Rules 2026.	**Yes/No**

Chris James
Group Manager Medsafe
Regulatory Services
Date: 7 May 2026

Hon David Seymour
Associate Minister of Health
Date:

Verification Pathway – finalising the rules and fees

Background

4. In April 2026, Cabinet agreed to introduce into the Medicines Regulations 1984 fees for applications to the Verification Pathway [CBC-26-MIN-0011 refers].

5. The Verification Pathway will enable expedited approval of medicines in New Zealand. It will use a high-trust model relying on assessment and approval by two recognised overseas regulatory authorities.

6. Consultation on the proposed draft Verification Pathway rules and guidelines finished on 10 April.

Draft LEG paper and regulations for fees

7. The draft Medicines (Fees) Amendment Regulations 2026 are attached as Appendix 1. The amendment is consistent with Cabinet's agreement to introduce fees [CBC-26-MIN-0011].

8. Also attached (Appendix 2) is a paper for the Cabinet Legislation Committee seeking authorisation for submission to the Executive Council of the Medicines (Fees) Amendment Regulations 2026.

Consultation on Verification Pathway Rules and guidelines

9. Medsafe consulted on the rules for 8 weeks, from 16 February to 10 April 2026, as required by the Medicines Act 1981. This consultation was primarily aimed at pharmaceutical companies intending to submit future new medicine applications to Medsafe under the Verification Pathway.

10. Medsafe received 31 submissions: 28 from pharmaceutical companies, two from industry organisations, and one from an independent pharmaceutical regulatory consultant.

Consultation on the rules

11. Most submitters either agreed or somewhat agreed with the proposed rule or sub-rule. However, there were extensive comments which Medsafe has carefully considered. As a result of the consultation, Medsafe has made changes to over half of the rules (with some changes being minor) and removed one rule.

Consultation on guidelines

12. Alongside the rules consultation, Medsafe also sought feedback on the draft guidelines. This was intended to minimise the burden on submitters and target the earliest implementation date for the pathway.

13. Medsafe is currently analysing comments on the guidelines and will publish the outcome following approval of the rules.

Other issues raised

14. Comments were also received on aspects of the pathway defined in the Medicines Amendment Act 2025, for example whether provisional/conditional approvals should be

included in the pathway. These aspects were considered by the Select Committee in their consideration of the Bill.

Notable areas of feedback relating to the rules

15. A focus of Medsafe and industry is that the pathway must be usable. Medsafe believes that the pathway rules balance enabling and encouraging applications against the need for suitable checks to be in place. Additionally, the ability to verify that the medicine for supply in the New Zealand market is identical to that approved and supplied overseas. The proposed rules ensure the pathway is both expeditious and robust.

16. The final proposal is largely harmonised with similar pathways in place in Singapore and the UK, and it is much faster. Medsafe commits to reviewing the rules and guidelines after experience with the pathway has been gained, to improve the pathway where possible.

17. Medsafe has relaxed some of the rules in response to feedback that preparing some of the required documentation is too onerous. Medsafe has considered other ways in which aspects of the medicine can be verified while maintaining the same level of assurance of quality, safety and efficacy. For example, the requirement to provide evidence of approval of changes to medicines since they were initially approved has been removed. Instead, applicants will only need to list these in a table of regulatory history, a more straightforward job for applicants that provides similar assurance for Medsafe.

18. There was mixed feedback regarding the time limit for applications granted from overseas approvals. The majority of respondents (over 60 percent) suggested either 1, 2, 3, or 4 years. The remainder suggested 5 years or over. Medsafe has aligned with the majority and considers that the period should be 4 years. This encourages market entry for new medicines in New Zealand rather than creating a pathway for legacy products. This is more permissive than the Singapore and UK pathways, where the time limit is 2 to 3 years.

19. Feedback suggested that medicines approved via international work-sharing pathways such as ACCESS and Project Orbis should be eligible for the pathway as two approvals. This has been discussed at length with industry during the development of the pathway and was considered by the Select Committee. Medsafe considers that medicines approved via these pathways are not excluded, provided that the applicant can provide two sets of assessment reports.

20. The abbreviated reliance pathway is also available for products that have been approved elsewhere, including via work-sharing procedures.

21. Industry requested a longer time for applicants to respond to any requests for information due to the time it takes them to liaise with their international colleagues and collate responses. Though Medsafe expects requests for information to be minor in nature, Medsafe agrees to extending this from 20 to 30 working days.

22. There were many questions regarding interpretation and definitions. Medsafe has updated the rules and drafted updates to the guidelines to provide greater clarity. In most cases, companies have interpreted the rules as being more restrictive than they are intended to be, therefore these updates are expected to be well received.

23. There were comments on operational and administrative processes, such as invoicing processes. These will be considered as Medsafe reviews feedback on the guidelines.

24. In addition, the consultation response from Medsafe reminds respondents that the abbreviated reliance pathway, based on one overseas approval, is still available to companies and is currently undergoing expansion to include more application types. Medsafe continues to meet and exceed performance targets for all application pathways.

Next steps

25. We will consult agencies on the draft LEG paper and draft regulations to introduce fees between 11 to 15 May. We anticipate ministerial consultation over a similar timeframe. Following agency and ministerial consultation, we will work with your office to finalise the paper for lodgement.

26. If you agree with the attached Verification Pathway Rules, we will publish them on the Medsafe website. We will work with your office on communications material for an announcement.

27. At the request of your office, we can provide you with talking points for the Cabinet Committee meeting.

Indicative timeline

Process step	*Date*
Lodge LEG paper	21 May
LEG meets	28 May
Cabinet and Executive Council	2 June
Fees regulations gazetted. If Minister agrees, final Pathway Rules can be published and announced, guidelines and CRIS published	4 June
Fees regulations and Rules come into effect	3 July

ENDS.

Appendix 1: Medicines (Fees) Amendment Regulations 2026

s9(2)(h)

Appendix 2: Draft Paper for Cabinet Legislation Committee – Medicines (Fees) Amendment Regulations 2026

Appendix 3: Outcome of consultation – verification pathway rules

Appendix 4: Verification Pathway Rules

s9(2)(h)